



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0617; FRL-9971-35]

FIFRA Scientific Advisory Panel; Notice of Public Meeting and Request for Nomination of Ad Hoc Expert Members

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day, in-person meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review the Resistance of Lepidopteran Pests to *Bacillus thuringiensis* (Bt) Plant Incorporated Protectants in The United States: EPA's Analysis of Scientific Uncertainties Related to Resistance Management and Options to Enhance the Current Insect Resistance Management Program. Preceding the in-person meeting, there will be a half-day virtual preparatory meeting, conducted via webinar using Adobe Connect, to consider and review the clarity and scope of the meeting's draft charge questions. Registration is required to attend this virtual meeting. The date and registration instructions will be on the FIFRA SAP website <http://www.epa.gov/sap> by mid-March to early April.

DATES: The virtual preparatory meeting will be announced in a future **Federal Register** Notice and on <http://www.epa.gov/sap>. The 4-day, in-person meeting will be held July 17 to July 20, 2018, from approximately 9 a.m. to 5 p.m.

ADDRESSES: *Meeting:* The location of the 4-day, in-person meeting will be announced in a future **Federal Register** Notice and on <http://www.epa.gov/sap>. The virtual meeting will be webcast. Please refer to the following website for information on how to access the webcast: <http://www.epa.gov/sap>.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0617, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

How to submit nominations, requests to present oral comments, and requests for special accommodations. Submit nominations of candidates to serve as ad hoc members of the FIFRA SAP Meeting, requests for special accommodations, or requests to present

oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Tamue L. Gibson, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-7642; email address: *gibson.tamue@epa.gov*.

Comments. Written comments should be submitted for both the virtual preparatory meeting and the in-person meeting on or before May 10, 2018. FIFRA SAP may not be able to fully consider written comments submitted after May 10, 2018. Requests to make oral comments should be submitted on or before May 24, 2018 by contacting the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. You may also subscribe to the following listservs to be notified when notices regarding this and other SAP related activities are published.

https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101,

<https://public.govdelivery.com/accounts/USAEPAPPT/subscribers/qualify>. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this review should be provided on or before [*insert date 30 days from date of publication in the **Federal Register***]. More information can be found under unit I.C.4., Request for nominations to serve as ad hoc expert members of FIFRA SAP for this meeting.

Webcast. The virtual preparatory meeting will be webcast only and registration is required. Please refer to the following website for information on how to access the webcast: <http://www.epa.gov/sap>. The 4-day, in-person SAP meeting may also be webcast. You may refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the webcast. Please note that the webcast for the in-person meeting is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to allow EPA time to process your request.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through regulations.gov or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

C. How May I Participate in both Meetings?

You may participate in both meetings by following the instructions in this unit. To ensure proper receipt of comments, nominations or other requests by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2017-0617 in the subject line on the first page of your request.

1. *Written comments.* Written comments for both the in-person and virtual meetings should be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before May 10, 2018, to provide FIFRA SAP the time necessary to consider and review the written comments. FIFRA SAP may not be able to fully consider written comments submitted after May 10, 2018.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP during the in-person or virtual meetings to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before May 24, 2018, to be included on the meeting agenda. Requests to present oral comments during the in-person meeting will be accepted until the date of

the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. Oral comments during the virtual meeting are limited to approximately 5 minutes due to the time constraints of this webcast. Oral comments during the 4-day, in-person meeting are limited to approximately 5 minutes unless arrangements have been made prior to May 24, 2018. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. In addition, each speaker should bring 15 copies of his or her oral remarks and presentation slides (if required) for distribution to FIFRA SAP at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the in-person meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc expert members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: field entomologists with expertise in the southern United States (U.S.) corn and cotton systems who are either corn earworm/bollworm (both systems), fall armyworm, and/or western bean cutworm experts; pesticide resistance modelers with a strong background in entomology, ecology, and population biology; insect resistance management experts; population biologists

understanding the life-history of corn earworm/bollworm, fall armyworm, and/or western bean cutworm; corn breeders, molecular biologists in the field of entomology with an understanding of the agricultural system in the southern U.S.; social scientists with expertise in resistance management issues and understanding of dynamics in the agricultural U.S. (e.g., human and market factors); and economists with expertise in the U.S. agricultural system and Bt technology-related issues. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER**

INFORMATION CONTACT on or before [*insert date 30 days from date of publication in the Federal Register*]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except EPA. Other factors considered during the selection process include availability of the potential Panel member to fully participate in the Panel's review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of

independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each Panel; therefore, selection decisions involve carefully weighing a number of factors, including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's peer review charge for this meeting, the Agency anticipates selecting approximately 13 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR Part 2634 -- Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks, and bonds, and where applicable, sources of research support. EPA will evaluate the candidate's financial disclosure form to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes and final report. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at

<http://www.epa.gov/scipoly/sap> or may be obtained from the OPP Docket at <http://www.regulations.gov>.

II. Background

A. Purpose of FIFRA SAP

The FIFRA SAP serves as one of the primary scientific peer review mechanisms of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on human health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix). The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). FIFRA established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

The purpose of the July 2018 SAP is for the Agency to present major risk factors believed responsible for expediting lepidopteran adaptation to Bt toxins in the U.S. and

associated scientific uncertainties. Furthermore, the Agency will discuss identified shortcomings of the current insect sampling methodologies, rearing and resistance testing of populations and the feasibility of successful mitigation when resistance is confirmed. In addition, the meeting serves to assess whether it is warranted scientifically to develop a resistance management plan for western bean cutworm. The overall goal of the meeting is to receive recommendations that reduce the resistance risks for lepidopteran pests, increase the longevity of currently functional Bt traits and future technologies, and improve the current insect resistance management program for lepidopteran pests of Bt corn and cotton.

Lepidopteran resistance to *Bacillus thuringiensis* (Bt) traits of corn and cotton were published by academic scientists for the continental U.S. in 2014 for the fall armyworm (*Spodoptera frugiperda*), in 2016 for the corn earworm (*Helicoverpa zea*), and in 2017 for the western bean cutworm (*Striacosta albicosta*). Likewise, industry reported resistance for the southwestern corn borer (*Diatraea grandiosella*) in their resistance monitoring reports to the U.S. EPA in 2016. The Agency identified several risk factors that may have had the greatest impact on these resistance developments. Some of these are: 1) lack of high dose traits; 2) use of single modes of action possible year-after-year; 3) corn seed blends in the southern U.S.; 4) poor refuge compliance for Bt corn in southern states; 5) continuous selection with same traits expressed in Bt corn and Bt cotton in a given year; 6) methodological approaches with monitoring for resistant field populations; and 7) challenges with identifying resistance using diet bioassays for non-high-dose pests. The Agency will discuss its analysis of identified risk factors underlying lepidopteran resistance development in the U.S. as well as associated scientific

uncertainties. Furthermore, the Agency will discuss its analysis of methodological issues with collecting insects from the field, rearing and testing populations for resistance, and the feasibility of mitigating field resistance for Lepidopteran pests.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, charge/questions to FIFRA SAP, and related supporting materials will be available by mid to late March 2018. In addition, a list of candidates under consideration as prospective ad hoc panelists for this meeting will be available for a 15-day public comment period by late March to early April 2018. You may obtain electronic copies of most meeting documents, including FIFRA SAP composition (i.e., members and ad hoc members for this meeting) and the meeting agenda, at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare the meeting minutes and final report approximately 90 calendar days after the in-person meeting. The meeting minutes and final report will be posted on the FIFRA SAP website: <https://www.epa.gov/sap> and may be accessed in the docket at <https://www.regulations.gov>.

Authority: 7 U.S.C. 136 *et. seq.*; 21 U.S.C. 301 *et seq.*

Dated: February 21, 2018.

Stanley Barone Jr.,

Acting Director,

Office of Science Coordination and Policy.

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